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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 09/813,429      | 03/21/2001  | Margot Mayer-Proschel | UT-0031             | 3502             |

7590

12/03/2003

Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, NJ 08053

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| EXAMINER |
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HAYES, ROBERT CLINTON

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1647

DATE MAILED: 12/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                       |  |
|------------------------------|------------------------|-----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>   |  |
|                              | 09/813,429             | MAYER-PROSCHEL ET AL. |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>       |  |
|                              | Robert C. Hayes, Ph.D. | 1647                  |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
     a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                               | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9/21/01</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election with traverse of Group I (claim 1) in Paper No. 9/15/03 is acknowledged. The traversal is on the ground(s) that "Applicants respectively disagree with the Examiner's characterization of these inventions as distinct", since they are "dependent from claim 1", and because "a proper search of the prior art relating to the method for isolating human neuroepithelial precursor cells of Group I would also reveal any prior art relating to uses of these cells such as set forth in the claims of Groups II-IV". This is not found persuasive because methods of transplantation, or nonhuman animals transplanted with neuroepithelial cells, are not limited to only the method of Group I to produce these cells; thereby, requiring a different search and different considerations for not only the claimed nonhuman animals, but also the different methods claimed, which require different method steps, different goals and different starting materials. Thus, an undue burden would be created for the Examiner to search and examine these distinct inventions, for the reasons previously made of record. The requirement is still deemed proper and is therefore made FINAL.

Claims 2-4 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9/15/03.

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2. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of isolating human neuroepithelial precursor cells from neural tissue (e.g., the neural tube) from human embryos after first culturing adherent cultures on fibronectin/laminin and then after using structurally known and definable antibodies to A2B5, NG2 and eNCAM, does not reasonably provide enablement for a method using any generic "human fetal cells" committed to a different tissue fate, or a method using antibodies to structurally and functionally uncharacterized epitopes/markers (i.e., NG2). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses on page 5 that "[h]uman fetal tissue is commercially available from fetuses age 14 to 20 weeks of age, a stage at which neurogenesis predominantly occurs", and that "methods used to isolate neuroepithelial precursor cells in nonhuman animals are not directly applicable to isolating human neuroepithelial precursor cells from commercially available sources of human fetal tissue". However, that claimed is not commensurate in scope with this disclosure, and instead encompass the use of any human fetal tissue at any stage of development, which the skilled artisan would not reasonably expect to result in the generation of neuroepithelial cells, without requiring undue experimentation to determine such, as currently claimed.

Second, although it can be argued that the disclosure on page 21 describes how to obtain functional antibodies to A2B5 and eNCAM in the claimed method, no disclosure on how to

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obtain the NG2 antibody is disclosed. Therefore, one skilled in the art would not know how to make Applicants' invention based on the limited guidance and description provided within the instant application without requiring undue experimentation to first discover what structurally and functional constitutes a NG2 antibody that may then work in the instant claimed method.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Culturing is normally carried out in medium (e.g., DMEM/F12 medium or serum free medium), versus in only "FGF and chick embryo extract"; thereby, being an incomplete recitation for the culturing conditions.

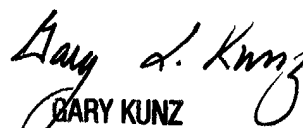
4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.  
November 25, 2003



GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600